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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,883

07/30/2003

Seth A. Foerster

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/630,883	Applicant(s) FOERSTER ET AL.	
	Examiner Brian Szmaj	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Oath/Declaration

1. This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. Claim 52 is currently added. Claim 52 contains subject matter similar to the preliminary amendment filed on July 30, 2003. This amendment claims subject matter that is not fully disclosed in the current specification. In particular, the current specification is silent with respect to using at least two imaging methods to detect the implanted mass, and the implanted mass is detectable for a first time period. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Priority

2. The Applicants claim priority to 08/308,097, filed on September 16, 1994. However, due to the fact that the above-mentioned claimed subject matter is not directly disclosed in the current specification, the current application is being treated as a Continuation-In-Part, with the effective filing date of July, 30, 2003.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the woven marker

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must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Figure 20 does not show a woven marker. See 112 rejection below.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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2. Claim 52 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 52 claims the marker element (the embodiment shown in Figure 20) expands when implanted in the biopsy site. The Applicant states the current specification provides support on Page 7, line 25 through Page 8, line 14. The cited location in the specification only provides support for a spring element that expands once placed within tissue. The specification fails to support any expansion of the embodiment as shown in Figure 20. Furthermore, the current specification fails to support a biodegradable material that has material properties that would allow the implant to expand once placed at the implantation site. The current specification clearly discloses the use of non-bioabsorbable radiopaque materials (metal). The current specification on Page 23, lines 4-6 discloses the markers could also be constructed of biodegradable radiopaque materials, but does not disclose the biodegradable materials must be capable of expansion.

3. Claim 52 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a marker that is bioabsorbable and detectable by an imaging system, does not reasonably provide enablement for a bioabsorbable mass that is detectable by at least two imaging methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

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The current specification does not disclose a marker that is imageable by at least two imaging methods. Page 6, lines 12-13 state "Visualization of the marker is readily accomplished using various state of the art imaging systems". These two lines do not support two separate imaging methods being capable of identifying a single marker element. At best, the disclosed lines only support the use of imaging a marker using a single imaging method depending upon the manufacture of the marker element to incorporate specific radiopaque or ultrasound-imageable or MRI-imageable material in each marker element; i.e. an individual marker would only be able to be remotely visualized by either x-ray or MRI or ultrasound, but not more than one imaging method.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear to the examiner what the broadest reasonable interpretation of "woven biodegradable material" (emphasis added). Applicant states in the specification on page 23, lines 2-6, Figure 20 is woven. However Figure 20 does not illustrate a woven apparatus. To the contrary, the figure appears to illustrate a completely unitary piece of material with material removed to provide a specific design. The Applicant is allowed to be his own lexicographer but the applicant is not allowed to use the meaning of a term outside the accepted meaning without expressly stating such is the case in the specification. MPEP 2111.01 (IV). The plain and ordinary meaning of the term woven,

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which is a past participle of "weave", is defined as "to interlace (strands) especially to form a texture, fabric, or design". See Merriam-Webster's Online Dictionary. See also MPEP § 2173.05(a).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (6,161,034) in view of Wolff et al (5,545,208).

Burbank et al disclose a means for marking a biopsy site and further disclose placing a mass or article of biodegradable material into the cavity site created by a biopsy, imaging the mass by at least two imaging techniques, and the marker remains detectable for a first period of time after the mass is introduced into the cavity. See Column 4, lines 59-62; Column 5, lines 47-64; Column 7, lines 47-67.

Burbank et al however fails to disclose a compressed woven mass of imageable biodegradable material.

Wolff et al discloses a biodegradable, self-expandable stent and further disclose the use of a contrast media for remote imaging. See Column 6, lines 62-63; Column 7, lines 25-28 and 45-49.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the marker element of Burbank et al to use an expandable biodegradable imageable woven article, as per the teachings of Wolff et al, since it would provide a means of marking a biopsy site that can be remotely imaged as well as being palpable to relocate the biopsy site.

Response to Arguments

8. Applicant's arguments filed May 15, 2009 have been fully considered but they are not persuasive. The Applicants argue the current specification clearly supports the claim limitation of detecting the marker by at least two imaging methods, and state page 1, lines 8-11 and page 6, lines 12-13 as support for the claim limitation. The Examiner, after reading the above cited lines, respectfully disagrees. The citation on page 1, lines 8-11, only disclose the means available to the oncologist to detect the presence of a suspected lesion. Furthermore, lines 9-10 state: "i.e. palpation, x-ray, MRI or ultrasound imaging". {emphasis added} These lines clearly state the use of only one type of imaging to detect the location of the suspected lesion, not "at least two remote imaging detection methods" for detecting a marker element. The citation on page 6, lines 12-13 states: "Visualization of the marker is readily accomplished using various state of the art imaging systems.". {emphasis added} The dictionary definition of "various" from Merriam-Webster Online Dictionary is "individual" or "separate". The Applicants are attempting to define "various" as "multiple", which is incorrect. Therefore, the current

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specification fails to support this claim limitation, and the priority date is being maintained as the filing date of this application, July 30, 2003.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736